

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-769

CHEMISTRY REVIEW(S)

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
HFD-540

AUG 29 1997

Review of Chemistry, Manufacturing, and Controls

NDA #: 20-769 CHEM. REVIEW #: 1 REVIEW DATE: 09-AUG-1997

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	30-AUG-1996	03-SEP-1996	11-OCT-1996
AMENDMENT/BC	20-DEC-1996	23-DEC-1996	30-DEC-1996
AMENDMENT/BC	15-MAY-1997	16-MAY-1997	20-MAY-1997
AMENDMENT/BL	02-JUL-1997	03-JUL-1997	

NAME & ADDRESS OF APPLICANT:

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DRUG PRODUCT NAME

Proprietary:

LOCOID Lipocream® (proposed)

Nonproprietary/USAN:

Hydrocortisone butyrate USP

Code Names/ #'s:

None

Chemical Type/

Glucocorticoid (4025010)

Therapeutic Class:

3 S

ANDA Suitability Petition/DESI/Patent Status:

N/A

PHARMACOLOGICAL CATEGORY/INDICATION:

Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

DOSAGE FORM:

Cream, lipophilic

STRENGTHS:

0.1%

ROUTE OF ADMINISTRATION:

Topical

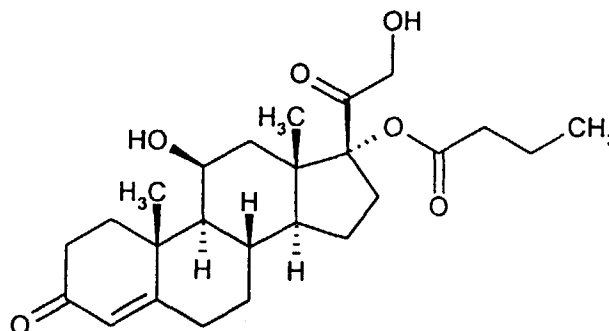
DISPENSED:

☒ Rx ☐ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT.:

- (a) Pregn-4-ene-3,20-dione, 11,21-dihydroxy-17-(1-oxobutoxy)-, (11 β)-
(b) cortisol 17-butyrate
(c) 11 β ,17,21-trihydroxypregn-4-ene-3,20-dione 17-butyrate

Molecular Formula: C₂₅H₃₆O₆
Molecular Weight: 432.56
Melting Range: 197-208°C
CAS Number: [13609-67-1]



SUPPORTING DOCUMENTS:

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Yamanouchi Europe B. V.

LOCOID Lipocream® (hydrocortisone butyrate 0.1%)

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NDA 18-514, LOCOID® Cream, 0.1%

NDA 18-652, LOCOID® Ointment, 0.1%

NDA 19-116, LOCOID® Lotion, 0.1%, Yamanouchi Europe B.V.

DMF

CONSULTS:

The proposed tradename, "LOCOID® Lipocream," was sent to the FDA Labeling and Nomenclature Committee (LNC) on 12-NOV-1996 for evaluation. On 12-JUN-1997, the LNC recommended that the term "Lipocream" be incorporated as part of the proprietary name, using either ® or ™ to distinguish the term from the dosage form.

The Establishment Inspection Request was submitted 04-MAR-1997 through the EES program. The facilities were judged acceptable by the Office of Compliance on 07-MAR-1997, signed (electronically) by Melissa Egas, HFD-322.

REMARKS/COMMENTS:

This drug product is a reformulation of currently approved and marketed drug LOCOID® Cream, NDA 18-514. The "Lipocream" formulation differs from the previous cream in the proportion of the inactive ingredients used, specifically having a smaller fraction of water.

CONCLUSIONS & RECOMMENDATIONS:

APPROVABLE

The application is approvable for manufacturing and controls under section 505 of the Act. All manufacturing facilities are currently in acceptable GMP compliance as of 07-MAR-1997

J. S. Hathaway, Ph.D.
Review Chemist, HFD-540

cc: Orig. NDA 20-769
HFD-540/DivFile
HFD-520/Micro/PSheldon
HFD-880/Biopharm/S-CLee
HFD-540/Chem/JSHathaway
HFD-540/MedOffr/PHuene
HFD-540/PharmTox/JAvalos
HFD-540/ProjMgr/OCintron
HFD-540/ChemTeamLdr/WHDeCamp

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APPROVABLE